IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

CINDY HENZEL Plaintiff, v. DANIEL J. STARKS, JOHN W. BROWN, RICHARD R. DEVENUTI, STUART M. ESSIG, THOMAS H. GARRETT III, BARBARA B. HILL, MICHAEL A. ROCCA, WENDY L. YARNO, STEFAN K. WIDENSOHLER, FRANK C-P YIN, PAUL BAE, Defendants, and ST. JUDE MEDICAL, INC., Nominal Defendant.	Court File No. _____ CLASS ACTION

VERIFIED SHAREHOLDER'S DERIVATIVE COMPLAINT

Cindy Henzel ("Plaintiff"), through her undersigned attorneys, alleges as follows on information and belief, except as to those matters that are personal to Plaintiff, which are alleged on personal knowledge:

NATURE OF THE ACTION

1. This is a derivative action brought by Plaintiff, a St. Jude Medical, Inc. ("St. Jude" or the "Company") shareholder, on behalf of St. Jude for its protection and benefit. The defendants are several St. Jude officers and directors ("Individual

Defendants"), under whose leadership the Company has been subject to lawsuits by Charles Donigian ("Donigan") and Jerry Hudson ("Hudson") on behalf of the United States of America, *United States of America ex rel. Charles Donigian v. St. Jude Medical, Inc.*, C.A. 06 CA 11166 (DPW) (D. Mass.) (the "Donigan Action"), and *United States of America ex rel. Jerry Hudson v. St. Jude Medical, Inc. et al.*, C.A. 06 CV 2152 (DAP) (N.D. Ohio) (the "Hudson Action"). The Donigan Action seeks treble damages and civil penalties arising from the Company's claimed involvement in a scheme ("Scheme") in violation of, *inter alia*, the Federal Civil False Claims Act, 31 U.S.C. §§ 3729, *et seq.* (the "FCA").[1] The federal government, after a lengthy five-year investigation, has recently moved to intervene in Donigan Action so that it may prosecute the charges. The goal of the instant derivative action is to prevent corporate insiders from shifting all responsibility for the Company's misconduct onto the backs of the innocent public shareholders, while they themselves walk away while paying nothing, and even voting themselves increased salaries and benefits.

2. The Hudson Action demonstrates the widespread nature of the illegality within St. Jude and that its management has caused St. Jude to become a serial violator of False Claims Act. Here, Hudson sought to recover damages and civil penalties arising out of the Company's alleged involvement in yet another scheme paying kickbacks to hospitals in Kentucky and Ohio to induce those institutions to purchase St. Jude devices

[1] In addition to raising an FCA claim, Donigan has also raised a retaliation claim under 31 U.S.C. § 3730(h) and a wrongful discharge claim under Missouri law against STJ for penalizing Donigan through physical threats and discharge.

("Ohio Scheme") in violation of, *inter alia*, the FCA.[2] The United States intervened in the Hudson Action and the case settled in early June, 2010, with St. Jude agreeing to pay $3.7 million to the United States.

3. This Complaint primarily addresses the Scheme, which allegedly tainted the treatment of many cardiac patients, and subjected seriously ill patients and others to unnecessary medical procedures designed to promote the use of St. Jude's medical products, including implantable defibrillators and pacemakers. According to the complaint in the Donigan Action, St. Jude is alleged to have provided kickbacks to induce healthcare providers, including cardiologists, to use the Company's medical products, and have the providers submit requests for reimbursement to U.S. government medical programs including Medicare and Medicaid. These illegal kickbacks took various forms including: (1) making payments to doctors ostensibly for services in connection with claimed legitimate post-marketing studies (which in fact were not), and which exposed patients to unnecessary medical procedures that were purposely designed and used as a means to increase the sale of the Company's medical devices; and (2) making payments to medical professionals for lavish entertainment and travel, as well as tickets to sporting events and concerts.

4. In addition, this Complaint also references the Ohio Scheme through which St. Jude offered illegal rebates and research incentives to induce hospitals to buy or use St. Jude's products. The kickbacks alleged in the Hudson Action included "retroactive"

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[2] In addition to his FCA claim, Hudson also filed claims under Ohio law for age discrimination, wrongful discharge, and breach of implied contract.

payments to hospitals in Ohio and Kentucky that were based on past purchase of St. Jude products, as well as payments to those hospitals that purchased competing products to try and induce the purchase of St. Jude products in the future. Instead of purchasing medical devices based on the best interests of patients, the hospitals involved in the Ohio Scheme conspired to purchase devices based on illegal kickbacks paid by St. Jude. Given the serial nature of the schemes, and the other evidence of management involvement in these schemes, it is impossible for defendants to deny their knowledge of these highly improper business practices.

5. Both schemes undermined the integrity of the medical profession by subjecting medical professionals and hospitals to bribes as referenced above, and denied numerous patients the benefit of professional services rendered in light of the patients' best interests as opposed to those of St. Jude or the hospitals and medical providers involved.

6. St. Jude's corporate compliance department, office of the general counsel, and compliance hotline had multiple opportunities to address the serious wrongdoing alleged presented by the schemes, yet no one at St. Jude, including the Company's officers or the Board of Directors took any action to either investigate, or stop the conduct alleged. The fact that St. Jude's management refused to even investigate the wrongdoing strongly suggests that not only did the Company's management have knowledge of the schemes, but that they in fact ratified the underlying conduct.

7. Because of the nature of the Scheme, the circumstances under which it arose and the *Qui Tam* action now pending against the Company which seeks millions of

dollars in damages, any pre-suit demand addressed to St. Jude's Board of Directors (the "Board") to bring claims relating to the Scheme against the responsible St. Jude officers, directors, employees and agents, cannot and would not be fairly considered by the Board. As discussed in more detail below, the St. Jude Board is unable to fairly address a pre-suit demand in this case. Under governing authority, demand is futile.

8. This action seeks redress against those officers, directors and others personally responsible for causing harm to the Company, and also seeks an injunction barring St. Jude's fiduciaries from failing to enforce professional disciplinary policies against executives who directed or acquiesced in any type of unlawful act.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000, exclusive of interest and costs, and the Plaintiff is a citizen of Pennsylvania and each defendant is a citizen of a state other than Louisiana. This action is not brought collusively to confer jurisdiction on this Court that it otherwise would lack.

10. This action is also brought pursuant to 28 U.S.C. § 1331 (federal question jurisdiction) because the factual allegations, the law and issues to be resolved are so intertwined with the currently pending *Qui Tam* action in Massachusetts that this case must properly be heard in federal court where key issues of federal law may be appropriately be decided.

11. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because St. Jude has its principal offices in this District and because acts and offenses pertinent to the causes of action stated herein were committed in this District.

THE PARTIES

12. Plaintiff is a shareholder of St. Jude has owned shares of St. Jude common stock throughout the entire relevant period and will continue to hold shares throughout the pendency of this action. Plaintiff is a citizen of Pennsylvania.

13. Nominal defendant St. Jude is a Minnesota corporation with its principal place of business located at One St. Jude Medical Drive, St. Paul, Minnesota 55117. The Company's stock is traded on the New York Stock Exchange under the ticker symbol "STJ." St. Jude develops medical technology and services for medical professionals who treat cardiac, neurological and chronic pain patients worldwide. The Company focuses its efforts in four areas including: (1) cardiac rhythm management; (2) atrial fibrillation; (3) cardiovascular; and neuromodulation. The Company's product portfolio includes implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy (CRT) devices, pacemakers, electrophysiology catheters, mapping and visualization systems, vascular closure devices, heart valve replacement and repair products, spinal cord stimulation and deep brain stimulation devices. St. Jude is a citizen of Minnesota.

14. Each of the Individual Defendants referenced below is a citizen of a state other than Louisiana for diversity jurisdiction purposes.

15. Defendant Daniel J. Starks, Jr. ("Starks") has served as the Chairman of the Board since 1996, and has served as St. Jude's President and Chief Executive Officer since 2004. Defendant Starks is a citizen of Minnesota.

16. Defendant John W. Brown ("Brown") has served as a director of St. Jude since 2005. He is the Presiding Director of the Company. Defendant Brown is a citizen of Minnesota.

17. Defendant Richard R. Devenuti ("Devenuti") has served as a director of St. Jude since 2001. Defendant Devenuti is a citizen of Massachusetts.

18. Defendant Stuart M. Essig ("Essig") has served as a director of St. Jude since 1999. Defendant Essig is a citizen of New Jersey.

19. Defendant Thomas H. Garrett, III ("Garrett") has served as a director of St. Jude since 1979. Defendant Garrett is a citizen of Minnesota.

20. Defendant Barbara B. Hill ("Hill") has served as a director of St. Jude since 2007. Defendant Hill is a citizen of Virginia.

21. Defendant Michael A. Rocca ("Rocca") has served as a director of St. Jude since 2004. Defendant Rocca is a citizen of Florida.

22. Defendant Wendy L. Yarno ("Yarno") has served as a director of St. Jude since 2002. Defendant Yarno is a citizen of New Jersey.

23. Defendant Stefan K. Widensohler was a director of St. Jude from 2001 to January 2010. Defendant Widensohler is a citizen of Germany.

24. Defendant Frank C-P Yin was a director of St. Jude from 2001 through 2005. Defendant Yin is a citizen of Missouri.

25. Paul Bae ("Bae") was the Vice President of Human Resources and Compliance Officer from 2006 through at least 2009, and General Counsel and Vice President, Human Resources for St. Jude Medical's US Division. Defendant Bae is a citizen of Minnesota.

FACTUAL ALLEGATIONS

26. The allegations in this Complaint derive from the First Amended Complaint filed March 12, 2007 in the Hudson Action, and the Third Amended Complaint filed January 19, 2010, in the Donigan Action. The United States has successfully moved to intervene in the Donigan Action as a result of its lengthy five-year investigation into the alleged wrongdoing by St. Jude.

A. Donigan Action

1. Relevant Medical Devices Manufactured by St. Jude

27. St. Jude manufactures two types of medical devices that are at issue in Donigan Action: pacemakers and implantable cardioverter defibrillators ("ICDs"), both of which have been the subject of multiple St. Jude post-market clinical trial studies. Post-market clinical trial studies are designed to assess the clinical performance of a medical device or pharmaceutical after that device or drug has been approved by the United States Food and Drug Administration ("FDA").

28. Pacemakers are battery-powered implantable devices that function to electrically stimulate the heart to contract and control abnormal heart rhythms. Pacemakers are typically implanted in patients with arrhythmias, which are problems with the rhythm or rate of the heartbeat.

29. An ICD is a small implantable device that looks similar to a pacemaker. The ICD detects arrhythmias and delivers electrical therapy-pacing pulses or defibrillation therapy as needed to control an abnormal heart rate. Where pacemakers typically increase a slower heart rate, ICDs are designed to slow down a heart that is beating too fast.

30. Medical device companies such as St. Jude sell products directly to healthcare providers (*e.g.*, hospitals and skilled nursing facilities). Government Healthcare Programs pay for these devices either under a bundled rate (which not only includes the cost of the devices, but also includes the cost of the implant procedures), or unbundled rate (paying for the devices themselves), depending upon the particular Government healthcare program's reimbursement plan. After implantation, there are follow up visits.

2. Government Healthcare Programs

31. In 1965, Congress enacted the Medicare Program, codified within Title XVIII of the Social Security Act, to pay for the costs of certain healthcare services. The program is overseen by the United States Department of Health and Human Services ("HHS") through the Centers for Medicare and Medicaid Services ("CMS"). Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services and durable medical equipment to persons over sixty-five (65) years of age and others that qualify under the terms and conditions of the Medicare Program based on disability or affliction with certain diseases. *See* 42 U.S.C. §§ 1395 to 1395ccc.

32. Upon discharge of a Medicare beneficiary from the hospital, the hospital submits an interim reimbursement claim for products and services provided to the patient.

33. In 1986, CMS issued a Medicare National Coverage determination providing limited coverage of implantable defibrillators (ICDs). The CMS policy has expanded over the years with revisions in 1991, 1999, and 2003, and finally a Medicare National Coverage decision memo for implantable defibrillators (CAG-00157R3) dated January 27, 2005 which greatly expanded Medicare coverage for ICDs.

34. Separate from Medicare, the Medicaid program, codified within Title XIX of the Social Security Act of 1965, 42 U.S.C. §§ 1396, *et seq.*, is a system of medical assistance for indigent individuals. Though created by federal statute, Medicaid is a federal-state program in which the United States provides a significant share of program funding. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify pursuant to Medicaid guidelines.

35. When healthcare providers enroll to participate in a state's Medicaid program, those providers agree to abide by the state's Medicaid manual. The Medicaid manuals for individual states typically incorporate the anti-fraud provisions of the Medicare Program (*see* discussion *infra*).

36. Some of the rules and regulations which enrolled providers in both the Medicare and Medicaid program agree to follow are to: (a) bill for only those covered services which are medically necessary; (b) neither bill for any services which were not performed or delivered in accordance with all applicable policies, nor submit false or

inaccurate information relating to provider costs or services; (c) not engage in any act or omission that constitutes or results in over utilization of services; (d) be fully licensed and/or certified under all applicable state and federal laws to perform the services provided; (e) comply with the applicable state and federal statutes, policies and regulations; and (f) not engage in any illegal activities related to the furnishing of services or products.

37. Provider hospitals participating in the Medicaid program are required to file annual cost reports with the state agencies administering that particular state's Medicaid program and are required to submit claim forms identical to those used in the Medicare program.

38. TRICARE Management Activity, formerly known as CHAMPUS, is a program of the United States Department of Defense that helps pay for covered civilian health care obtained by certain military beneficiaries, including retirees, their dependents, and dependents of active-duty personnel. *See* 10 U.S.C. §§ 1079, 1086; 32 C.F.R. Part 199. TRICARE contracts with fiscal intermediaries and managed care contractors to review and pay claims, including claims submitted by St. Jude pursuant to the TRICARE program.

39. The Office of Personnel Management ("OPM") is an agency of the United States responsible for, among other things, administering the Federal Employees Health Benefits Program ("FEHBP"). FEHBP provides health care benefits for qualified federal employees and their dependents. (Together the programs described above in the

preceding paragraphs shall be referred to as "Federal Health Care Programs" or "Government Health Care Programs").

40. Reimbursement practices under all Government Health Care Programs closely align with the rules and regulations governing Medicare reimbursement. One of the fundamental requirements for reimbursement eligibility under Medicare, Medicaid and other Government Health Care Programs is that the medical service provided must be reasonable and medically necessary. *See, e.g.,* 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1396, et seq.; 42 C.F.R. § 410.50. Medical providers are prohibited from billing the government for medically unnecessary services or for procedures performed solely for the profit of the provider. *See id.*

41. As described more fully below, each of the Government Health Care Programs requires providers that seek payment from the program certify compliance with the provisions of the federal Anti-Kickback Statute (discussed *infra*) and with other federal laws governing the provision of health care services in the United States. For example, physicians and hospitals enter into provider agreements with CMS to establish their eligibility to seek reimbursement from the Medicare Program. As part of those agreements, without which the hospitals and physicians may not seek reimbursement from Federal Health Care Programs, the provider must sign the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute

> and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

Form CMS-855A; Form CMS-8551 (effective 2001). Further, the claims themselves as submitted contain a similar certification. *See, e.g.,* Form CMS-1500.

42. When a participating provider submits a claim for payment, he or she does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law, to include without limitation the Anti-Kickback Statue. In the case of Medicaid, each State's Medicaid Program's applicable certifications also incorporate relevant state law.

43. St. Jude sold the medical devices at issue in Donigan Action to hospitals and other institutional healthcare providers (hereafter "Health Care Professionals" or "HCPs"). These HCPs received millions of dollars in Medicare, Medicaid, TRICARE and other Government Healthcare Program reimbursements and monies for these devices. In turn, the physicians and other HCPs who purchased and prescribed such devices while participating in the phony trials and registries described herein and receiving the unlawful inducements described herein, received millions of dollars for their services, in addition to the phony trial/registry payments, and unlawful inducements.

3. Relevant Legal Background

44. The FCA provides, in pertinent part that any person who:

> (a) (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; . . . or

> (a) (1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . .
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, . . . plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729. On May 20, 2009, the FCA was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"). Section 3729(a)(l)(B) was formerly § 3729(a)(2), and is applicable by virtue of § 4(f) of FERA, while § 3279(a)(l) of the statute prior to FERA, and as amended in 1986, remains applicable here.

45. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), FCA civil penalties were adjusted to a range of between $5,500 and $11,000 for violations occurring on or after September 29, 1999.

For purposes of the FCA,

> The terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729(b).

46. The FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States government provides any portion of the money or property which is requested or demanded, or if the government will reimburse

such contractor, grantee, or other recipient for any portion of the money or property which is requested. 31 U.S.C. § 3729(b)(2).

47. The Medicare and Medicaid Patient Protection Act, also known as the federal Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b) ("AKA"), prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical items or services, including items or services provided under the Medicare, Medicaid, and TRICARE programs. In pertinent part, the AKA states:

> Whoever knowingly and willfully offers or pays [or solicits or receives] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony.

42 U.S.C. § 1320a-7b(b).

48. The AKA seeks to prohibit such activities in order to secure proper medical treatment and referrals, and to limit the possibility of a patient having to undergo unnecessary treatments or having to accept specific items or services which are based not on the needs of the patient, but on the incentives given to others, thereby limiting the patient's right to choose proper medical care arid services.

49. The AKA was created due to congressional concern that the remuneration and gifts given to those who can influence health care decisions corrupts medical

decision-making and could result in the provision of goods and services that are more expensive and/or medically unnecessary or even harmful to a vulnerable patient population.

50. The AKA was strengthened by amendments in 1977 and 1987 which, *inter alia*, increased the civil monetary penalties of $50,000 per violation (42 U.S.C. § 1320a-7a(a)(7)), and three times the amount of remuneration paid, regardless of whether any part of the remuneration is for a legitimate purpose. 42 U.S.C. § 1320a-7a(a).

51. Concern about improper marketing practices prompted the Inspector General of the Department of Health and Human Services to issue a series of Special Fraud Alerts in 1994 concerning various practices that could run afoul of the AKA. *See* Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 29, 1994); *see also* Fed. Reg. Dec. 19, 2004. In one Fraud Alert issued in October 1994 (and contained in the above), the Inspector General stated, *inter alia*,

> Generally, a payment or gift may be considered improper . . . if it is:
>
> - Made to a person in a position to generate business for the paying party;
> - Related to the volume of business generated; and
> - More than nominal in value and/or exceeds fair market value of any legitimate service rendered to the payer, or is unrelated to any service at all other than referral of patients.

Inspector General scrutiny may be warranted for example for:

> Grants to physicians and clinicians for studies of prescription products when the studies are of questionable scientific value and require little or no actual scientific pursuit. The grants may nonetheless offer substantial benefits based on, or related to, use of the product.

52. In May 2003, the Inspector General of HHS published further guidance on marketing practices which may constitute kickbacks known as the "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," 68 Fed. Reg. 23731 (May 5, 2003) (the "OIG Guidelines"). In those Guidelines, the 010 further addressed "Research Funding" as follows:

> Manufacturers often contract with purchasers of their products to conduct research activities on behalf of the manufacturer on a fee-for-service basis. These contracts should be structured to fit in the personal services safe harbor whenever possible. Payments for research services should be fair market value for legitimate, reasonable, and necessary services. *Post marketing research activities should be especially scrutinized to ensure that they are legitimate and not simply a pretext to general prescriptions of a drug. Prudent manufacturers will develop contracting procedures that clearly separate the awarding of research contracts from marketing. Research contracts that originate through the sales or marketing functions-or that are offered to purchasers in connection with sales contracts—are particularly suspect.*

Id. at 23735-36 (emphasis added).

53. As described above, compliance with the AKA is a precondition to participation as a health care provider under a Government Health Care Program, including Medicare Medicaid. Moreover, compliance with the AKA is a condition of payment. As noted above, reimbursement practices under all Government Health Care Programs closely align with the rules and regulations governing Medicare reimbursement, and each of the Government Health Care Programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the AKA and with other federal laws governing the provision of health care services in the United States. Put another way, if a provider tells CMS or its agent

that it provided services in violation of the AKA (or another relevant law), CMS will not pay that claim. Provider agreements as well as the claims themselves contain a certification of compliance with all Medicare laws, regulations, and program instructions including the AKA. *See, e.g.,* Form CMS-855A; Form CMS-8551 (effective 2001); Form CMS-1500.

54. When a provider submits a claim for payment, he or she does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law, to include without limitation the AKA. In the case of Medicaid, each State's Medicaid Program's applicable certifications also incorporate relevant state law.

4. St. Jude's Institutional Understanding of the Anti-Kickback Act

55. Defendant St. Jude and its employees were aware of the obligations of the AKA. They understood that it was a violation of the AKA to offer or to pay remuneration, by whatever means, to induce customers like hospitals or doctors to purchase or to recommend the purchase of St. Jude's devices.

56. For example, after the Inspector General Guidance was published, the Advanced Medical Technology Association ("AdvaMed") adopted in September 2003 (effective January 1, 2004), a "Code of Ethics on Interactions with Health Care Professionals" ("the Code" or the "AdvaMed Code") purportedly to guide its members on voluntary compliance with the AKA. At that time, AdvaMed was the trade organization for approximately 1,100 manufacturers of medical devices, diagnostic products, and medical information systems, including St. Jude.

57. The AdvaMed Code addressed, inter alia, member-sponsored product training and education, supporting third party educational conferences (through grants, meals, hospitality and expenses), sales and promotional meetings, arrangements with consultants, including for research, gifts, providing reimbursement and other economic information, grants and other charitable donations. The Code made it clear that research and consulting services should be for *bona fide* consulting services with compensation consistent with fair market value and the payments must be to support "genuine medical research" with "scientific merit".

58. AdvaMed expected that: "Members will communicate the principles of this Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code." However, AdvaMed also cautioned that: "All Members have an independent obligation to ascertain that their interactions with Health Care Professionals comply with all applicable laws and regulations. The information provided by the Department of Health and Human Service Office of Inspector General, as well as applicable laws or regulations, may provide more specificity than this Code, and Members should address any additional questions to their own attorneys." AdvaMed Code pp. 5-6 (September 3, 2003).

59. St. Jude adopted the AdvaMed Code in September 2003, effective January 1, 2004, and began training its employees regarding the Code. The Code is incorporated in St. Jude's "USSD Policies, Procedures and Guidelines Manual" effective January 1, 2004. St. Jude clearly recognized that its actions were governed by the AKA. For example, the St. Jude Manual states:

> St. Jude Medical has adopted the AdvaMed Code of Ethics on Interactions with Health Care Professionals (the AdvaMed Code). In addition to the AdvaMed Code, the St. Jude Medical Code of Business Conduct dealing explicitly with "Relationships with Physician and Customers" and the Medicare Anti-kickback Law also govern this area.

60. Notwithstanding St. Jude's understanding of the AKA, and Donigan's alerting company officials to the ongoing misconduct on several occasions between 2005-2007, at the direction of Defendants, St. Jude repeatedly violated the AKA in its relationships with Health Care Professionals by paying them sham fees for phony post-market clinical research studies, and by inundating them (and in some cases their family members) with lavish presents, including entertainment, travel, vacations, temporary staff, tickets to sporting events, and "educational" events at luxury resorts. These kickbacks had the intended effect of causing providers to order or prescribe St. Jude products and devices instead of competitors' products, all at the expense of patients' wellbeing and government monies.

5. Kickbacks to Healthcare Professionals

61. Donigan worked as a Technical Service Specialist ("TSS") in the Cardiac Rhythm Management Division ("CRMD") of St. Jude. The CRMD was part of the United States Sales Division, which division offers cardiac resynchronization therapy devices, implantable cardio-defibrillators, pacemaker leads, introducer systems, and device programs used to treat certain cardiac arrhythmias. There are over 1,000 sales representatives and about 300-500 TSS's in the CRMD division. The CRMD is one of 5 St. Jude product category corporate divisions. Donigan was part of West Central West

("WCW"), which comprises the States North Dakota, South Dakota, Minnesota, Illinois, Missouri, Iowa, Wisconsin, and Nebraska. WCW is broken down into 6 regions, "WCW1 through WCW5 and WCW-AF," of which Donigan was in WCW2, the St. Louis and mid-Missouri areas. The Senior Regional Director of these 6 regions was Doug Helm; below him were about 8-10 sales representatives and below them were approximately 14 TSS's, one of whom was Donigan.

62. St. Jude's entire United States sales force (consisting of between 1,300-1,500 people) was a given virtually unlimited budget for marketing while Donigan worked there. For example, Donigan alleges that he knows of one person in his area who had a weekly expense account of about $5,000 (i.e. over $250,000/year). This exorbitant budget enabled the sales force to provide essentially unlimited incentives to physicians to order pacemakers and ICDs and to enroll patients in and participate in studies/registries, and to reward physicians for doing so, no questions asked. In addition, Donigan alleges that he is aware of many examples of lavish entertainment, including but not limited to, payment of airline tickets, conference fees, baseball tickets, gourmet wine, lavish meals, trips, and vacations.

6. Phony Post-Market Registries, Studies and Trials as Kickbacks

63. The Scientific Studies Organization ("SSO") is a department within St. Jude. SSO on the surface conducted the post-market clinical studies described below. Each territory is assigned a Field Clinical Engineer ("FCE") from SSO, to maintain contact with the physicians concerning the studies/clinical trials. In practice, the St. Jude sales force maintained the contact with the physicians too; in fact, the sales force often

filled out the phony trial paperwork, with the physician having no involvement in data input, all as more fully described below.

64. The FCEs were integrally involved with sales, not science. The FCEs actively supported and worked with the sales force to have as many targeted physicians as possible involved in clinical trials/studies. An email to Donigan (and others) from St. Jude management, is illustrative:

> FCE Utilization
>
> We demonstrated an excellent working relationship with the FCE Team throughout the RHYTHM ICD clinical trial. This is substantiated by the North Midwest Area's top position nationally in total implants for the study. I feel that the communication level between the CRM Team and FCE Team....and our ability to function as an integrated Team....are at the highest levels.

65. The clinical trials described herein were clearly designed and implemented only for the purpose of paying physicians to prescribe St. Jude's products, not for actual scientific research. The sales force handling these bogus studies had every incentive to perpetuate them, as they earned more money as more clinical trial patients were enrolled. This is confirmed in writing, for instance, in a management e-mail to Donigan: "[C]linical trial devices will count toward the tier level. Pricing of clinical trial devices will be priced separately outside of this agreement."

66. Although the sales force earned commissions, sales of devices that were associated with a phony trial meant that the sales representative would have his commission reduced by approximately 20% of the cost of the study, to offset the payments made by St. Jude to physicians. For example, if a payment was made to a

physician in the amount of $1,500, then the sales representative was responsible for $300 of the cost of the study, through commission reduction.

67. Not only would physicians prescribe the St. Jude devices for patients who did not previously have a pacemaker, they also prescribed the St. Jude devices as replacements for competitors' (*e.g.*, Guidant, Medtronic) pacemakers. Once the patient's device reached its "elective replacement indicator", the switch was made to the St. Jude product. This was done by doctors to receive study money.

68. Certain cardiologists selected St. Jude devices based upon the existence of a trial/study, so that if they could use a device which was the subject of a trial/study/registry, they would receive additional payment from St. Jude, in addition to professional fees.

69. Certain cardiologists billed Medicare and other insurers for the St. Jude study visits, even though they performed little or none of the work required by the study protocol, as described below. These same doctors instructed St. Jude employees in preparing "superbills" so the doctors could submit claims to Medicare/Medicaid, and St. Jude employees would prepare such superbills despite St. Jude's Code of Conduct seemingly prohibiting them from assisting with reimbursement or billing paperwork.

70. Certain cardiologists also failed to fill out the proper paperwork and/or to perform the required services despite what they agreed to as part of the research study agreement, the investigator's agreement, or the protocol. Instead, certain members of the St. Jude sales force performed these tasks, putting into question the integrity of the study data.

71. Donigan's supervisor, Doug Helm, was the Senior Regional Director for WCW; with responsibility over Missouri, Illinois, Kansas and Nebraska, permitted or even required the sales force under his supervision to engage in this misconduct. The conduct Donigan was personally aware of in his area was also ongoing in the rest of Mr. Helm's region. As described below, St. Jude management was aware of the misconduct, but did not take adequate steps to stop, correct, or prevent the misconduct.

a. AWARE Trial (Analysis of a New AT/AF Detection Algorithm in Patients with Atrial Arrhythmias

72. AWARE was one of the St. Jude phony trials used to promote its medical devices and to prove incentives to doctors.

73. AWARE is an acronym for "Analysis of a New AT/AF Detection Algorithm in Patients with Atrial Arrhythmias." The AWARE Trial involved two pacemaker models: (1) Identity ADx DR 5380, advertised as the "world's smallest dual-chamber, rate-responsive pacemaker;" and (2) Identity ADx XL DR 5386, advertised as "dual—chamber, rate responsive, extended longevity pacemaker." Among other things, the trial documentation notes that the patient's "insurance company will be billed for all procedures or tests that are standard medical treatment for your condition."

74. The AWARE Trial was nothing more than a shell operation to bribe physicians to prescribe the above pacemakers. To achieve this goal, millions of dollars were paid to physicians across the country. Physicians received $700 for the initial implant of the pacemaker, and $100 for each follow-up visit for the pacemaker, usually done at 1, 3 and 6 months.

75. This purportedly "scientific" study lacked adherence to the most basic scientific protocol, as the inclusion and exclusion criteria (see § 3.3.1 of the Study Plan) were blatantly ignored. Approximately 30% of the patients had no history of the inclusion criteria of Atrial Tachycardia (AT) or Atrial Fibrillation (AF). Instead, these patients were diagnosed with AV nodal block (Heart block 1st, 2nd and 3rd degree) and were enrolled in the studies on that basis alone.

76. Similarly, the exclusion criteria (see § 3.3.2 of the Study Plan) were ignored, as patients with terminal cancer and who were expected to live only a few months at best were implanted with pacemakers and put into the trial.

77. At no time did Donigan receive notice from SSO that any patient did not qualify and/or was rejected from the AWARE trial. This is not surprising, given that arguably biased sales representatives would determine whether a patient was qualified to participate in the trial.

78. The AWARE trial expressly contemplates physicians' diagnosis and treatment for the "study" subjects. For instance, § 3.1 of the Study Plan states that "The *physician* will provide a clinical diagnosis for all documented episodes on the case report form at *each* visit based on any of the following sources: stored electrograms, surface E.C.G.'s, and/or device diagnostics." (emphasis added). Physicians, however, had little to no involvement or participation in the "study."

79. The articulated "purpose of study" as set forth in § 1.2 of the Study Plan, "is to evaluate the incidence of AT/AF and inappropriate detection of AT/AF events in patients with a history of AT or AF. The AT/AF detection algorithm data and AT/AF

detection triggered stored EGMs will be compared with the *physician's* clinical diagnoses." (emphasis added). Despite the physician's stated critical role in the trial, the St. Jude sales force completed the trial paperwork. If they did not possess certain information, as was often the case, they made it up. For instance, at implant, one question concerns what medications the patient is taking. The sales force would answer this question by copying the medications written in the patient surgical chart from implantation. The sales force did not have access to this chart for the 1, 3, and 6 month follow-up. The sales force would copy the medications written in the enrollment form, because they did not have access to the charts in the doctors' offices. There were instances that medications had changed, but were improperly noted on the paperwork.

80. The sales force signed the doctor's signature on the forms or obtained the doctor's signature on a blank form. After the sales force completed the data, a copy of the study paperwork was to be shipped to SSO, and a copy was also kept on file in the physician's office. Donigan alleges that he is aware of at least one instance where the study paperwork was still not returned to the SSO some 6 months after the patient's visit.

81. AWARE enrollments stopped in December 2005. Donigan was told that the quota was met. Although St. Jude's internal records in 2006 showed a Registry with a number of 1,200 patients in the AWARE Trial (due to a cap), Donigan at one point observed records indicating 1,500 or more patients in the trial. St. Jude funded this kickback program with at least 1.5 million dollars in payments to physicians.

82. Donigan alleges that he is aware of numerous patients affected by the above-described misconduct who were treated by certain physicians. These doctors were

never present for the 1, 3, or 6 month follow-up visit; instead Donigan was expected to meet with the patients and complete the paperwork. (Examples of these patients (with names redacted for privacy) are attached to the Complaint in the Donigan Action at Exhibit 3). All or virtually all of these patients were covered by Medicare by virtue of their age, or by another Government Healthcare Program. Doctors also instructed the St. Jude sales force to complete "superbills" for their patients' study visits to obtain reimbursement from Government Healthcare Programs. Certain doctors instructed Donigan to do so and he did.

b. ACT Registry (ADVANCEMNT IN ICD THERAPY)

83. The ACT Registry was a sham post implant study.

84. According to the "Registry Plan," "[a]ny patient that receives an FDA-approved STJ ICD or CRT-D is eligible for enrollment into the registry." Patients were to be followed for a period of 24 months after implant, with data collected at enrollment, and also at 6, 12, 18 and 24 months and at any unscheduled follow-up visits. During the follow-up visits, arrhythmic episode diagnoses, device data and stored electrograms were to be collected. Section 3.2 of the Registry Plan provides that 5,000 patients were to be enrolled.

85. Physicians participating in the sham ACT Registry received a total of $2,000 ($500 each for enrollment and $375 each for the follow-up visits, scheduled at 6, 12, 18, and 24 months), and physicians across the country received millions of dollars. The stated purpose for the physician payments is "for the legitimate reimbursement of

time, effort, and oversight by the Investigator and the professional staff"; yet, the St. Jude employee performed these tasks. For example:

> On or about September 16, 2006, an FCE from SSO was in the office of Dr. MK with Donigan. The FCE had Dr. MK sign blank case report forms that were later filled out by Donigan and the FCE from patient charts.
>
> On or about September 19, 2005, a STJ TSS filled out a study form for a patient identified as "COLLAW" (to protect patient privacy, the study forms identified patients by a "name" that was comprised of the first 3 letter of the patient's last name and the first 3 letters of the patient's first name), an 81 year old male implanted with an ICD on or about March 2, 2005. The TSS also rubber stamped the signature of Dr. MK. On the form, the "Current Drug Therapy" section was not filled in and section number 5, "Clinical Diagnoses" was not answered. Dr. MK was paid $500 by STJ for the submission of this form in addition to what she was reimbursed by Medicare.
>
> On or about March 21, 2006, the follow up form was filled out by an FCE from SSO and also rubber stamped with Dr. MK's signature. Dr. MK was paid $375 by STJ for this follow up visit in addition to what she was reimbursed by Medicare.
>
> Another follow up data form for patient COLLAW was filled out by the FCE from SSO on or about October 17, 2006. The FCE had Dr. MK sign a blank form before the patient came in. The form as filled out later by the FCE listed the patient on two drugs, Lasix and Coreg, and then in the number 3 section "Drug Therapy adjusted" box was marked "no". However, it should have been marked "yes' because the prior visit forms listed no drugs for this patient. Again, Dr. MK was paid $375 by STJ for this follow up visit in addition to what she was reimbursed by Medicare.
>
> Similar misconduct occurred with respect to a patient known as "LUTWIL", a 78 year old male who had an ICD implanted on or about March 23, 2005. The enrollment form was incomplete and inaccurate and the signature may not be that of Dr. MK. Dr. MK was paid $500 by STJ for the enrollment of this patient and also billed Medicare.
>
> At the follow up on or about October 17, 2005, an STJ TSS filled in the data which inaccurately stated that there was no drug adjustment, and rubber stamped the doctor's signature. Dr. MK was paid $375 by STJ for this follow up visit in addition to what she was reimbursed by Medicare.

> Patient LUTWIL's follow up on or about April 18, 2006 was done by an STJ FCE from SSO, but again, Dr. MK was paid and billed Medicare.
>
> The patient's follow up on or about October 17, 2006 was also done by the FCE. Dr. MK signed a blank follow up data form prior to the patient visiting. The FCE incorrectly marked the number 6 box (which asked for any changes at the previous follow up visit) "no" even though the prior visit forms showed on line number 6 that the device had been reprogrammed and changes were made to the tachycardia parameters. Dr. MK was paid $375 by SIM for this follow up visit and billed Medicare for the ICD follow up.

86. In or about January 2006, CMS established a mandatory ICD registry. *See* "Report of a New System of Records", 70 FR 72437 (Dec. 5, 2005). The data to be reported is substantially identical to the data reported under the ACT Registry, which started in January 2004.

87. St. Jude funded the ACT kickback program with at least $10 million in payments to physicians.

88. Donigan claims to know of numerous patients exposed to the above misconduct. In addition, some of the patients were enrolled in the study even though they were outside the specified 45 day window (past the implant date) as required by the protocol. A true copy of a list of ACT Registry patients (with patient full names omitted by St. Jude for privacy reasons) when Donigan was employed at St. Jude is attached to the Complaint in the Donigan Action at Exhibit 5). Many of these patients were treated by certain doctors known to Donigan. All or virtually all of these patients listed in Exhibit 5 were covered by Medicare, by virtue of their age, or by another Government Healthcare Program. Doctors also instructed the St. Jude sales force to fill out "superbills" for their patients' study visits to attain reimbursement from Government

Healthcare Programs. For example, Drs. MK and TMcD instructed the sales force to do so, and they did; on or about September 19, 2006, Dr. MK instructed Donigan on filling out her superbill prior to her billing Medicare/Medicaid. All claims specifically identified for said specifically identified patients from the specifically identified implant date through at least the term of the study are false claims caused by St. Jude.

c. PROVE Trial – Programming Ventricular Tachycardia Therapy in Patients with a Primary Prevention Implantable Cardioverter-Defibrillator Indication

89. The PROVE Trial was yet another bogus St. Jude study.

90. Patients are eligible for the PROVE Trial - Programming Ventricular Tachycardia Therapy in Patients with a Primary Prevention Implantable Cardioverter-Defibrillator Indication study once they are scheduled to have an ICD implanted.

91. According to the Study Plan, the purpose of the study "is to determine if turning ATP therapy 'ON' (as part of the VT Therapy) can successfully stop VT episodes before they become VF, which is more serious." The PROVE Study Information and Consent Form notes that the patient's insurance company will be billed for all procedures or tests that are standard medical treatment, including the costs of the ICD device and implantation procedure, and the follow-up doctor visits.

92. The study was supposed to last for one year after enrollment, with follow-up appointments at 3, 6 and 12 months. Although physicians typically have no involvement with the study, they are paid hundreds of dollars for each patient. Often, there was no scientific value to the "study" results, because, *inter alia*, of improper programming at enrollment, and no-shows by patients.

93. The "Research Subject Information and Consent Form" provided to patients misleadingly stated: "You do not have to participate in this study to receive treatment for your condition. You can have the standard ICD implantation and programming done without being in the study."

94. St. Jude funded this kickback program with at least $10 million in payments to physicians.

95. Donigan claims he is aware of numerous patients affected by the above-described types of misconduct. For example, he has knowledge of patients "REYLAR" and "MEROLI" who were treated by Dr. MK. Dr. MK signed blank forms (e.g., on or about September 19, 2006) and a TSS and/or an FCE filled in the data on the form. On one occasion, Donigan was shown a stack of patient charts by an FCE and told that the FCE had to go through them later. Again, STJ paid Dr. MK.

96. Virtually all of the patients enrolled in PROVE were covered by Medicare by virtue of their age, or by another Government Healthcare Program. Doctors also instructed the St. Jude sales force to complete "superbills" for their patients' study visits to obtain reimbursement from Government Healthcare Programs. For example, Drs. MK and TMcD instructed the sales force to do so, and they did, including on or about September 19, 2006, when Dr. MK instructed Donigan on doing so.

d. The RARE Trial

97. The RARE trial was another phony trial used as a vehicle by St. Jude to bribe medical professionals.

98. The RARE trial evaluated the incidence of AF in patients with Sinus Node Dysfunction ("SSS") by comparing the Auto Mode Switch ("AMS") with the AMS triggered electrograms ("EGMs").

99. One of the lead investigators of the study was Dr. AH. The study was ongoing when Donigan began working at St. Jude and ended in early 2005. St. Jude's SSO published posters AB-15-2 and AB9-1 in May 2005 that falsely named Dr. AH as the author. In fact, St. Jude created these posters and Dr. AH merely presented them at the annual meeting of the prestigious Hearth Rhythm Society ("HRS"). Nothing further was done with the data.

100. Despite Dr. AH's minuscule role in the RARE Trial, Dr. AH and other physicians received $1500 per patient enrolled in the study. In total, millions of dollars were paid to physicians across the country. (*See* Exhibit 3 to the Complaint in the Donigan Action which contains examples of patients who were enrolled in the RARE study).

e. RATE Registry (Prevalence of AT/AF in the CRM Device Population)

101. The RATE Registry was another ploy to improperly pay money to medical professionals by St. Jude.

102. The purpose of the Rate Registry according to the Registry Plan, "is to produce a prospective, outcome-oriented registry to document the prevalence of atrial fibrillation (AF) in the [Cardiac Rhythm Management] CRM population by using the Advanced AT/AF Diagnostics in select STJ devices."

103. The study started around October 2006 and it was a prospective, two year data collection registry.

104. Eligible patients are those "that receive a St. Jude Medical (STJ) CRM device with advanced AT/AF diagnostic capabilities (Victory®, Epic®, Atlas® II, or comparable future devices.)" The less expensive St. Jude devices that also have the advanced AT/AF diagnostic capabilities are not eligible for the study. Further, there is no difference in diagnostics: the Rate Registry ICD devices vibrate and beep, while the less expensive models that do not qualify for the study only vibrate if an alert indication is met. For example, alert indications include high impedance of the right ventricle lead, or battery voltage at "end of life."

105. Data is supposed to be collected at implant and quarterly, for a total follow-up duration of 24 months.

106. Reimbursement to physicians was $1600 per patient: $400 for enrollment, $200 each for 6, 12, 18, and 24 month follow-up visits, and $100 each for 3, 9, 15 and 21 month follow-up visits. Millions of dollars were paid to physicians throughout the country. Dr. MK was one of the doctors involved in the study. As with other studies described above, the St. Jude sales force had doctors such as Dr. MK sign blank patient study related forms.

107. In addition to inducing doctors to sign off on study forms that they did not actually complete, St. Jude encouraged and/or required doctors to use more expensive St. Jude devices (such as Victory, Epic II, Atlas II, or comparable devices coming out in the

future) and did not inform doctors of the option of using a less expensive device with the same advanced diagnostic capabilities (e.g., Integrity, Epic, Atlas).

f. Other Trials As Kickbacks

108. The SSO endangered the lives of patients and defrauded the government through a plethora of other trials, including: Determine, WBC-MRI, RethinQ, Pas, Freedom, and Response H.F. In December 2007, Donigan learned that the top 15 enrolling sites across the United States for the Freedom trial had a total of 159 patients. These sites include Long Island Heart Associates in New York; Cardiology and Arrhythmia Consultants in Rochester Hills, Michigan; Jeffrey Goodman in Los Angeles, California; Cardiovascular Associates in Birmingham, Alabama; and Sentara-Norfolk General Hospital in Norfolk.

7. Entertainment (And Other Inducements) As Kickbacks

109. As alleged above the entire St. Jude sales force of approximately 1,300 to 1,500 employees was given unlimited an unlimited marketing budget. This plethora of funds allowed the St. Jude sales force to provide incentives to doctors to order pacemakers and ICDs, and to enroll patients in and in studies/registries and to reward doctors for doing so, no questions asked, as described herein.

110. In addition, Donigan is aware of many examples of lavish entertainment, including but are not limited to, payment of airline tickets, conference fees, baseball tickets, gourmet wine, lavish meals, payment for seating at the Lake Regional Ball, and fishing trips, including but not limited to a fishing trips to Canada. These kickbacks had the intended effect of influencing physicians to order STJ products For example:

a. In Spring 2005 (March/April), St. Jude Senior Sales Representative Jack Conner bought airline tickets for Las Vegas for Dr. MK and his wife. Conner also paid for the HRS Conference fees and hotel. Donigan was present when Conner gave Dr. MK an envelope in his office to pay for the trip.

b. On May 19, 2005, St. Jude Senior Sales Representative Jack Conner purchased St. Louis Cardinals baseball tickets costing over $200 from a broker. These tickets were to send Dr. AH's son to the St. Louis at Kansas City baseball game.

c. In August 2005, Dr. JH received St. Louis Cardinal baseball tickets for referring pacer/ICD cases to Dr. AH. St. Jude Technical Service Representative (TSS) Mel Wyatt purchased the tickets online through the Cardinal Prime Seat Club. Donigan was present when Wyatt delivered the tickets to Dr. AH (for Dr. JH). Donigan was also present at a lunch when St. Jude Senior Sales Representative Conner reimbursed Wyatt for the purchase of the tickets.

d. In August 2005, St. Jude Senior Sales Representative Jack Conner delivered a case of wine to the Moberly Regional Medical Center catheter lab manager, SC. Donigan was present in the lab doing an implant when Conner delivered the wine to the break room.

e. On August 24, 2005, St. Jude Senior Sales Representative Jack Conner and Jason Zitzer arranged for a physician, Dr. BL from Washington University in St. Louis, to come to the University of Missouri to present at Grand Rounds. Connor left the Grand Cru Steakhouse restaurant his credit card number to purchase dinner for three physicians (the speaker Dr. BL, Dr. RW and Dr. GF) and their wives.

f. In September 2005, St. Jude Senior Sales Representative Jack Conner purchased a $2,500 fishing trip to Canada for Dr. AH and stated he had done this for the last three years. Conner also stated that he had paid $500 for a table at the Lake Regional Ball for the Lake Regional catheter lab staff.

g. In October 2006, St. Jude Senior Representative Jack Conner paid $500 for a table at the Lake Regional Ball for Dr. MK's and Dr. TMcD's staff to attend.

111. St. Jude also provided or facilitated other kickbacks, including providing physicians and other providers with "Grants", and with temporary staff for their offices.

112. St. Jude also bribed physicians to induce other physicians to prescribe St. Jude products under the guise of the "HF Referral Program" and the "EP Implanter Program."

113. St. Jude provided kickbacks to physicians in Electrophysiology Fellowship Programs (EP Fellows) around the country. (EP Fellows are physicians who have already completed a Cardiology fellowship who then go on to an electrophysiology). St. Jude indicated in its internal marketing materials that a single EP Fellow physician, after graduation, with a conservative utilization of St. Jude products, will generate $2.7 million annually. (The "Class" of 2007 EP Fellows (100 MDs) $270 million annually -$1.4 billion over five years.) St. Jude spent or was expected to spend in 2007 a total of $158,172,579 from both the CRM Division and the AF Division, for its Fellows program.

114. Fellows Symposiums are normally held on a quarterly basis by St. Jude at luxury resorts. They provide education/marketing, plus help to place the EP Fellows. In order to place the EP Fellows, St. Jude also conducts "core practice searches" for Fellows, helping Fellows to be placed in medical practices. St. Jude's "educational department" also furnished a Board review for the NASPE Exam. (The Heart Rhythm Society administered this Examination of Special Competency in Cardiac Pacing and Cardioversion Defibrillation). The Board review is done in December, prior to the Heart Rhythm Society Meeting which is in April/June. St. Jude even had a "Fellows Manager" with whom the St. Jude sales department was supposed to work closely.

115. Previous Fellows Symposiums include one on February 2, 2007 at the Ritz Carlton in Phoenix, Arizona and another on May 8, 2007 at the Marriott in Denver, Colorado. St. Jude also utilized "CAB Meetings," where St. Jude flew in Fellows for a weekend meeting.

116. It was common practice to supply a hospital with introducers for free and allow the hospitals to bill for them. St. Jude assumed the cost of the free goods, and C Codes needed by the hospital so that they could get reimbursement from Medicare.

117. Also, every time a device was implanted it was common practice to buy lunch or dinner for the staff of the catheter lab. At Moberly Regional Medical Center, Dr. AH also requested that his office get lunch from St. Jude if one of its devices was implanted at the hospital. Also, anytime a device clinic was done at the doctor's office it was practice to provide lunch to the office staff.

8. St. Jude's Knowledge of the Illegal Activity

118. As a TSS for St. Jude, Donigan was responsible for assisting with the marketing, sale and distribution of cardiovascular medical devices, which included managing the completion of any required paperwork and patient enrollment documents related to the AWARE Trial, ACT Registry, and other studies.

119. As noted above, Donigan received training from St. Jude on compliance issues. As a Registered Nurse in the State of Missouri Donigan was held to the Nurse Practice Act which the Board of Nursing can revoke a license if the licensee is found guilty of a crime in which the essential element of fraud or dishonesty is part of the offense.

120. In October 2005, Donigan began to question with his co-workers St. Jude's practice of filling out the study paperwork and signing for doctors. Unbeknownst to Donigan at the time, the news media was reporting that on or about October 25, 2005, the United States Attorney's Office for the District of Massachusetts, had issued subpoenas or was otherwise investigating St. Jude regarding various issues relating to implantable cardioverter defibrillators (ICDs) and pacemakers, including: "sales practices," illegal payments or other inducements, possible violations of the Anti-Kickback Act and false claims statutes, relationships with doctors, use of incentives to doctors to use the device maker's products, and making excessive payments to doctors to enroll patients in post marketing evaluation studies of their devices (using product surveys) as a way of increasing sales.

121. When his co-workers' advice regarding internal practices did not match with Donigan's understanding from his St. Jude training, Donigan contacted Mr. Paul Bae, St. Jude's Vice President of Human Resources and Compliance Officer, and spoke with him in late October/early November 2005 to report his concerns with the manner in which the AWARE Trial and ACT Registry paperwork and patient enrollment documents were completed. Based on that conversation, Donigan understood that it was improper for the sales force to fill in any information except identifiers such as facility name or patient's name on the top of the forms. Rather, the physician or his staff needed to fill in the collected data, and the physician was to sign as the investigator. Donigan's co-workers disagreed with his understanding.

122. Thereafter, Donigan and other members of the sales force attended a presentation called "Legal Minefield." After that presentation, Donigan contacted the presenter, Neal Williams, St. Jude's Associate General Counsel in the corporate legal department, on November 15, 2005. Donigan's meeting with Mr. Williams did not change his understanding. Donigan's understanding remained the same as after his conversation with Mr. Bae: i.e. that he should not fill out enrollment and data collection forms even if the study center would sign the form—doing so would put the integrity of the study data at risk. In other words, Donigan's understanding was that neither he nor anyone else who was part of the sales force was to complete the ACT Registry or AWARE Trial patient enrollment documents, data collection forms, or implant information reports.

123. Despite this, Donigan's supervisor, Doug Helm, ST. JUDE's Regional Sales Manager for the WCW area, continued to require Donigan to complete the AWARE Trial and ACT Registry patient enrollment documents, data collection forms, and implant information reports. Other St. Jude co-workers openly criticized Donigan saying he was causing the Company harm and saying things to the effect of "DOJ is going to see the e-mail and question what we were doing." Donigan responded that "if what the company was doing was legal then there shouldn't be any issue."

124. In December 2005, one of Donigan's co-workers told Donigan he was sending him some new forms they could properly fill out for the studies. Upon receipt, Donigan noticed that the forms were the same as before, except there was not a place for signature by the physicians. Donigan again contacted Mr. Williams. Thereafter, Donigan

understood that he could *not* fill out any forms the doctors agreed to submit as part of the research study agreement, the investigator's agreement, or the protocol.

125. During this time Donigan responded to an e-mail from Mr. Kevin O'Malley (from the St. Jude General Counsel's office) asking (routinely) if he knew of any St. Jude Policy violations; Donigan checked yes. A reply e-mail indicated that someone from the General Counsel would be in touch with Donigan if they had further questions. When no one followed up with Donigan, he called St. Jude's hotline number and reported numerous of the violations alleged herein.[3]

126. In February 2006, Donigan again contacted Mr. Bae to report concerns with the manner in which the AWARE Trial paperwork and patient enrollment documents were completed. At this time and also in April 2006, Donigan reported incidents of workplace retaliation by co-workers based on Donigan's prior reports of compliance violations. In the interim, in March 2006, his supervisor Doug Helm gave him negative marks in his annual performance review because of his communications about the study paperwork and other illegal kickbacks.

127. Donigan also reported to management the common use of improper and illegal kickbacks by the St. Jude sales force including the improprieties concerning the AWARE trial and ACT Registry. These reports included many of the kickbacks described herein.

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[3] In fact Mr. O'Malley was St. Jude's long time Vice-President, General Counsel and Corporate Secretary. *See, e.g.* St. Jude's Annual Report on Form 10-K for the year ending December 31, 2003 at p. 16.

128. While employed with St. Jude, Donigan repeatedly questioned, investigated, and reported internally and subsequently to appropriate Government officials, St. Jude's illegal practices.

129. St. Jude refused to change its policies and practices that obligated Donigan to acquiesce in, or actively participate in violation of Medicare and Medicaid compliance requirements and the Federal Anti-Kickback Law. That the actions of St. Jude of which Donigan was complaining can constitute the basis for an FCA violation is confirmed by a press release issued December 23, 2009, by the United States Attorney's Office for the District of Massachusetts, in which the government announced that it had reached a $22 million civil settlement with Boston Scientific Corporation to resolve allegations that its subsidiary, Guidant Corporation, a competitor of St. Jude's, used post-market studies as vehicles to pay kickbacks to induce physicians to implant Guidant pacemakers and defibrillators.

130. Individual Defendant Bae had direct knowledge of the Scheme through Donigan's reports to him in late October/early November 2005, of concerns with the manner in which the AWARE Trial and ACT Registry paperwork and patient enrollment documents were completed.

131. The Individual Defendants may be reasonably inferred to have known of the Scheme or consciously disregarded it, given its prevalence throughout St. Jude, the large sums of money expended, and the need for approval of the Company's budgets and strategic plan.

9. **False Claims**

132. In legitimate FDA registered clinical trials, physicians do not bill a patients' insurance company (including Medicare or Medicaid) for the underlying physician services or products used. Similarly, products or pharmaceuticals used in legitimate FDA registered clinical trials are generally donated by the manufacturer; not billed to the patients' insurance company (including Medicare or Medicaid).

133. As a result of St. Jude's kickbacks to Health Care Professionals, as alleged above, St. Jude caused such professionals to submit false and fraudulent claims to government Health Care Programs or to make or use false records or statements material to false or fraudulent claims paid or approved by the government. Examples of patients for whom such false claims and/or false statements were made are described above and also are listed in Exhibits 3 and 5 to the Complaint in the Donigan Action. The claims for these specifically identified patients that were submitted to Medicare during and after the specifically identified kickbacks were paid by St. Jude, are false claims.

B. **The Hudson Action**

1. **St. Jude's Unlawful Kickbacks**

134. Hudson became employed with St. Jude in February 2004 and worked as a regional sales manager. In his position, Hudson had responsibility for overseeing district salespeople, ensuring their compliance with company policy and industry standards, and supporting employees responsible for medical device sales.

135. During his employment, Hudson observed Company efforts to use research incentives to regain access to formerly lost business, to persuade healthcare providers to use St. Jude products, and to increase Company market share.

136. For example, in an effort to regain business from the Veterans Administration ("VA") Medical Center, St. Jude expected its sales force to offer physicians clinical studies and/or provide St. Jude devices to physicians without following a formal waiver procedure.

137. The Company also used participation in clinical trials to as a means to coax physicians to use up or "burn off" products sold in bulk quantities that remained unused near the end of a sales quarter. By way of limited example, in 2005 St. Jude tried to offer clinical studies to doctors at various Cleveland hospitals in an apparent effort to convince them to use up previously purchased St. Jude products.

138. In an effort to increase sales of its cardiac rhythm management ("CRM") devices to the Cleveland Clinic Foundation ("CCF") (a Cleveland hospital), St. Jude offered to provide CCF with an Endocardial Solutions Inc. ("ESI") mapping system if the doctors at this hospital would agree to "drive increased CRM units" despite concerns from those physicians that such an arrangement would be prohibited by the hospital's legal department. St. Jude's efforts were successful, and in 2005 CCF's physicians committed to implanting one St. Jude ICD every day with a total of "5 ICD's per week or 2 CRT's and 3 to 4 ICD's per week as need to help with the acquisition of the ESI/St. Jude System." St. Jude also offered similar arrangements to other Ohio hospitals.

139. In 2005, St. Jude also directed salespeople to explore ways to leverage its ESI system to increase CRM sales and sales of electrophysiology ("EP") devices. If hospitals refused to commit to the sales, they were to be told that their ESI system would be removed. According to Hudson's complaint, several hospitals in Ohio agreed to commit to CRM and EP sales in exchange for the continued placement of the ESI systems.

140. Because St. Jude was well aware of the impropriety of conditioning research participation on product sales, Company policy was to prohibit employees from making reference to clinical study activities in e-mail correspondence and monthly reporting.

141. St. Jude also offered hospitals and doctors rebate incentives to induce future purchases of St. Jude products. For example, in 2004, St. Jude proposed a "rapid rebate" program to CCF. Under the terms of the program, if CCF agreed to the purchase of a certain quantity of St. Jude products, the hospital would receive an initial 3% rebate on products which were purchased in the prior quarter and an additional rebate on the same products if implanted in the current quarter. The same year, St. Jude offered a similar arrangement to Parma Community General Hospital ("Parma") in which Parma would receive a $400 rebate per ICD on the hospital's total purchase if the product was implanted within 60 days of receipt and another quantity of ICDs was ordered prior to the end of the quarter.

142. According to the complaint in the Hudson Action, St. Jude engaged in a practice of providing "consulting" opportunities to physicians that committed to using St.

Jude products. The physicians received monetary payments for their commitment to use St. Jude products. For example, according to the complaint, in April 2005, Dr. Bruce Stambler received "consulting" fees from St. Jude with regard to the implantation of CRT devices in two patients in January and February 2005.

143. St. Jude also engaged in a practice of exchanging grant and charitable support for the increased use of its products. In 2005, for example, St. Jude offered Drexel University College of Medicine a $100,000 donation to the college's Congestive Heart Failure Program in exchange for the purchase of St. Jude products.

2. Hudson's Reporting of Unlawful Activity

144. Hudson verbally questioned many offers made to St. Jude customers and objected to Company practices when he believed that standards, guideline or statutory obligations were being ignored.

145. As a result of his questioning of company practices, Hudson was systematically excluded from customer interaction and was eventually terminated.

3. False Claims

146. As a direct result of St. Jude's fraudulent practices and inducements in connection with the distribution and sale of its products, claims for payment in connection with such sales were rendered false or fraudulent.

147. To conceal its improper policies and practices, St. Jude made or caused to be made false and/or fraudulent records statements and omissions either directly or indirectly to obtain payment for products and services sold to the United States.

148. The Company also caused private health care providers, including the hospitals described in the Hudson complaint, to submit false and/or fraudulent claims for reimbursement to Government Healthcare Programs.

4. Government Intervention and Settlement

149. On May 19, 2010, the United States Department of Justice successfully intervened in the Hudson Action. The intervention came almost four years after Hudson filed his initial complaint and after a lengthy investigation by the United States Attorney's Office.

150. Shortly thereafter on June 4, 2010, the United States Attorney's Office for the Northern District of Ohio announced a settlement with St. Jude wherein St. Jude paid $3.7 million dollars. The press release issued by the U.S. Attorney's Office in connection with the settlement stated:

> Hospitals should base their purchasing decisions on what is in the best interests of their patients...We will act aggressively to ensure that choices about health care are not tainted by illegal kickbacks.
>
> The Department of Justice is committed to requiring that federal healthcare monies are properly spent...This case illustrates the necessity of oversight of federal health care programs in the United States.

DEMAND IS FUTILE

151. Pre-suit demand on the St. Jude Board to take action against those responsible for the wrongdoing described above has not been made and is not required because such demand would be futile under the circumstances. The present Board

consists of eight directors. Of these, at least seven were directors coincident with the wrongdoing alleged herein.

152. In the exercise of their duties, there is a strong inference that a majority of the St. Jude Board knew or consciously disregarded that St. Jude was engaging in widespread, systematic schemes to reap as much revenue as possible from the sales of medical devices through despite the inevitability of injuring patients, defrauding the government and undermining the honesty of the medical profession and the patients' right to honest services.

153. Here the schemes described above required the expenditure of hundreds of millions of dollars which could not have been expended absent approval by the Board of the Company's strategic plans permitting such funds to be expended. Such actions do not reflect a reasonable exercise of business judgment and raise a substantial likelihood of the Individual Defendants' personal liability. Demand is therefore futile and thus excused. Indeed, both the office of the St. Jude general counsel and the corporate compliance function was repeatedly informed of wrongdoing, all to no effect. The St. Jude sales department had unlimited funds to use to effect phony device trials and to repeatedly bribe physicians, coerce hospitals, and to take such action to expand the schemes as far as possible. The only reasonable inference under these circumstances is that St. Jude executive management and the St. Jude Board either explicitly knew of the wrongdoing and acquiesced in it, or consciously disregarded their duty to investigate and halt these unlawful practices.

154. Demand is also excused for the independent reason that the St. Jude Board is unable to fairly assess a shareholder demand. In light of the pending Donigan Action, (where the government has recently intervened), it is not possible for the directors in this case to objectively consider demand pursuant to their fiduciary duties. If the Board initiated actions against the Individual Defendants or others in this case, then St. Jude's efforts would be undermined or compromised in defending the pending Donigan Action.

155. As set forth at p. 8 of the Company's Quarterly Report on Form 10-Q, the Company has announced that it intends to vigorously defend the Donigan action. The Board cannot "vigorously defend" on one on hand and fairly consider a demand that would by definition compromise that defense on the other:

> *Boston U.S. Attorney Investigation*: In October 2005, the U.S. Department of Justice (DOJ), acting through the U.S. Attorney's office in Boston, commenced an industry-wide investigation into whether the provision of payments and/or services by makers of ICDs and bradycardia pacemaker systems (pacemakers) to doctors or other persons constitutes improper inducements under the federal health care program anti-kickback law. As part of this investigation, the Company has received three subpoenas from the government requesting documents regarding the Company's practices related to ICDs, pacemakers, lead systems and related products marketed by the Company's Cardiac Rhythm Management (CRM) operating segment. The Company has cooperated with the investigation and has produced documents and witnesses as requested. In January 2010, the U.S. District Court for the District of Massachusetts unsealed a qui tam action (private individual bringing suit on behalf of the U.S. Government) filed by a former employee containing allegations relating to the issues covered by the subpoenas. Although in December 2009, the DOJ had declined to intervene in this qui tam suit, the DOJ filed a motion in August 2010 to intervene....A hearing is scheduled for late October 2010. *The Company will vigorously defend against the allegations in the lawsuit.*

156. Additionally, in St. Jude's Motion to Dismiss filed June 22, 2010, St. Jude's directors attempted to secure dismissal of the Donigan Action by having arguing

that Donigan was disqualified under the Qui Tam Act (which requires discovery of the wrongdoing by a Donigan) because he was purportedly relying upon *public* revelations of ST. JUDE's wrongdoing and investigation regarding such wrongdoing –*viz.,* through a news article published in the *New York Times* on Sept. 27, 2005; and through a *Wall Street Journal* Article published on October 25, 2005. (Motion to Dismiss at 5-6.) Incredibly, the brief then admits that: "These newspaper articles make public the essential elements of Donigan's claim." *Id.* at 6. Even more telling is St. Jude's next argument—that Donigan's observations and reporting of wrongdoing relate largely to alleged acts occurring and continuing even *after the widespread public reporting of St. Jude's improper conduct. Id.* at 8. Put another way, in an attempt to obtain a technical dismissal of Donigan's claims, St. Jude paints a picture of continuing and brazen wrongdoing *subsequent to* the revelation of the contours of the wrongful scheme in the news media—facts that would have certainly been known to the Individual Defendants. Thus, the Board cannot conceivably deny knowledge of the wrongful schemes, and cannot reasonably deny their failure to rein in those schemes even after public disclosure of all their elements. They thus face a substantial likelihood of liability for consciously failing to halt the wrongdoing. Accordingly, demand is futile and thus excused.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
(Breach of Fiduciary Duty against the Individual Defendants)

157. Plaintiff repeats and realleges each and every allegation above as if set forth in full herein.

158. This claim is brought against Individual Defendants who consciously and in bad faith refused to thoroughly investigate and address wrongdoing at St. Jude.

159. St. Jude reaped profits, at the expense of injuring patients and defrauded the federal government, through the intricately planned program of bribing physicians, hospitals and other healthcare providers (hereinafter sometimes collectively referred to as "providers") with kickbacks to induce them to prescribe certain medical products the Company manufactured and sold, and causing the providers to submit requests for payment for these products to various government healthcare programs. Additionally, the Board failed to rein in, ameliorate or countermand such conduct.

160. As a result of the foregoing conscious disregard of Individual Defendants' fiduciary duties, St. Jude paid a multi-million dollar settlement to the United States, is exposed to continuing litigation and faces the threat of very substantial treble damages and civil penalties, as well as strictures on how it operates its business.

161. The Individual Defendants consciously disregarded their duties to manage the Company in a lawful manner despite their obligation to do so, and despite their obligation to inform themselves of key facts concerning how the Company was being run. They either consciously and in bad faith failed to do so, or knew that the Company was engaged in illegal conduct and ratified it, or consciously failed to address it.

162. The Individual Defendants are liable for all damages caused by their bad faith failure to discharge their fiduciary duties of loyalty, due care and oversight.

SECOND CAUSE OF ACTION
(Unjust Enrichment against Defendant Starks)

163. Plaintiff repeats and realleges each and every allegation above as if set forth in full herein.

164. Because of the wrongs committed herein, Defendant Starks reaped undeserved profits in the form of incentive compensation. This enrichment was at St. Jude's expense, and at the expense of feeble patients who should not have been subjected to medical procedures, and government funding.

165. Based on the failure to legitimately achieve the Company's financial and business goals, any payments, bonuses, grants and other elements of compensation Defendant Starks received were not properly awarded for the work performed and the results achieved.

JURY DEMAND

Plaintiff demands a trial by jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Against all of the Individual Defendants for the damages sustained by St. Jude as a result of the breaches of fiduciary duties, as set forth herein;

B. Equitable and/or injunctive relief as permitted by law;

C. Restitution and disgorgement of unjust enrichment;

D. Attorneys fees and costs; and

E. Any such other and further relief as may be just and proper.

Dated: September 21, 2010 **LOCKRIDGE GRINDAL NAUEN P.L.L.P.**

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VERIFICATION

Cindy Henzel, under pain and penalty of perjury under the laws of the United States, avers that as plaintiff herein she verifies that he has reviewed the foregoing Shareholder's Derivative Complaint, and that the allegations are true and correct to the best of her information, knowledge and belief.

Cindy Henzel